5. 510(k) Summary

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510(k) SUMMARY

510(k) Owner	Tenex Health 26902 Vista Terrace Lake Forest, CA 92630 Phone: (949) 580.1266 Fax: (949) 580.1270
Contact person	David Salzberg Tenex Health 26902 Vista Terrace Lake Forest, CA 92630 Phone: (949) 580.1266 Fax: (949) 580.1270 Email: Salzberg@tenexhealth.com
Date summary was prepared	November 21, 2012
Primary Product Code:	
Common Name	Ultrasonic Surgical Aspirator
Trade Name	TX1 Tissue Removal System
Classification Name	Instrument, Ultrasonic Surgical
Regulation	Unclassified
Class	Unclassified
Panel	General & Plastic Surgery
Product Code	LFL
Secondary Product Code:	
Common Name	Ultrasonic Surgical Aspirator
Trade Name	TX1 Tissue Removal System
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation	878.4400
Class	2
Panel	General & Plastic Surgery
Product Code	GEI
Predicate	K101561 TX1 Tissue Removal System

Description

The TX 1 Tissue Removal System is an ultrasonic surgical aspirator that emulsifies and removes soft tissue. The system consists of a console, ultrasonic handpiece, and foot pedal. The console provides control over the four user functions including irrigation, aspiration, cutting, and coagulation. It has a large, color LCD and employs a touch-screen for selection of required settings. The console provides audible tones for confirmation of selections. The console also houses the irrigation and aspiration pumps, thereby eliminating the need for a dedicated service cart or suction/waste source within the operating room. The console provides a connection for a commercially available cautery pencil or forceps. Two USB ports and one Ethernet port are available for loading software upgrades.

The ultrasonic handpiece connects to the console for power, as well as for delivering irrigation fluid directly to the surgical site and for removing emulsified tissue by way of integrated tubing set. The handpiece is constructed from various polymers and metals, while the tubing is made of biomedical grade PVC. The handpiece and tubing are provided sterile. The handpiece is a single use disposable component of the system.

Irrigation fluid is delivered under pressure to the surgical site by operation of an air pump residing in the console. The regulated output of the air pump pressurizes a cuff that is fitted around the irrigating fluid bag, thus providing irrigation at a fixed pressure regardless of the height of the fluid bag.

The foot pedal is used to control each of the four functions (irrigation, aspiration, ultrasonic fragmentation/emulsification, coagulation) of the system. It offers on/off functionality and is rated IPX5 (by the supplier) for protection against liquids.

Intended Use

The TX1 Tissue Removal System is intended for use as an Ultrasonic Surgical Aspirator of soft tissue.

Indications for Use

The TX1 Tissue Removal System is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

Technological Characteristics

The predicate and the TX1 Tissue Removal System were compared in the following areas and found to have similar technological characteristics and to be equivalent:

Principle of Operation
Method of tissue emulsification
Tip Amplitude
Method of aspiration (vacuum)
Vacuum level
Method of irrigation
Irrigation Flow
Electrical Safety standards met
Electrical
INPUT VOLTAGE
POWER CONSUMPTION
LINE FUSES
MAX. OUTPUT VOLTAGE (CUTTING)
MAX. OUTPUT VOLTAGE (FOOT PEDAL)
Irrigation
FLUID DELIVERY
VALVE TYPE
CONTROL
Cutting
HANDPIECE TYPE
CONTROL
SYSTEM PRIMING
Aspiration
ASPIRATION PUMP
AVAILABLE MAX. VACUUM LEVEL
AVAILABLE FLOW RATE
CONTROL
Coagulation
TYPE
OPERATING FREQUENCY
MAXIMUM POWER OUTPUT
HANDPIECE TYPE
CONTROL
Console Dimensions
HEIGHT
WIDTH
DEPTH
WEIGHT
LCD Touch Panel Display

The predicate and the TX1 Tissue Removal System were compared in the following areas and found to have minor different technological characteristics. The following differences have been determined to not have any impact on the safety or efficacy of the TX1 Tissue Removal System:

Material in contact with tissue
Pressure relief valve (console)
Sterilization, handpiece
Accessories
Electrical
MAX. OUTPUT VOLTAGE (COAGULATION)
Irrigation
OPERAT ING PRESSURE
Cutting
HANDPIECE TYPE
AVAILABLE POWER DELIVERY
OPERATING FREQUENCY

The following non-clinical performance tests were conducted:

Integrity test – Case body/Case tail joint interface PASS
Functional verification – post sterilization PASS
Functional verification – accelerated aged conditioning PASS
Functional verification – post transportation conditioning PASS
Cart strength verification PASS
EMC and General Electrical Safety PASS

- IEC 60601-1- 2 (2004): Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests PASS
- IEC 60601-1 (1999): Medical Electrical Equipment – Part 1: General Requirements for Safety, includes Amendment 1 (1991) and Amendment 2 (1995) PASS
- IEC 60601-2-2 (2006): Medical Electrical Equipment Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment.

Biocompatibility PASS

- ISO 10993-1:2009/Cor. 1:2010: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process PASS
- ISO 10993-5:2009: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity PASS
- ISO 10993-10:2010: Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization PASS
- ISO 10993-11:2006: Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity PASS

Conclusions from non-clinical performance data

After performing non-clinical performance studies, the data shows that the TX1 Tissue Removal System is substantially equivalent to the predicate as an Ultrasonic Surgical Aspirator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Tenex Health
% Mr. David Salzberg
Director, Quality and Regulatory Affairs
26902 Vista Terrace
Lake Forest, California 92630

March 20, 2013

Re: K123640
Trade/Device Name: TX_1 Tissue Removal System
Regulatory Class: Unclassified
Product Code: LFL
Dated: February 19, 2013
Received: February 28, 2013

Dear Mr. Salzberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number (if known): K123640

Device Name: TX1 Tissue Removal System

Indications for Use:

The TX1 Tissue Removal System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.03.19 11:58:39 -04'00'

for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K123640